

Notice of Allowability

Application No.

10/807,034

Examiner

Jacob Cheu

Applicant(s)

OAS ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/8/2006.
2. ☒ The allowed claim(s) is/are 23-40, 125-127 now renumbered as claims 1-21.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>7/20/2006</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Daley on July 20, 2006.

The application has been amended as follows:

Please replace claim 23 with the following amended claim -

23. A method of detecting a binding event involving a test protein with a test ligand, the method comprising:

- (a) providing an unpurified test protein;
- (b) providing a test ligand;
- (c) contacting the test ligand with the unpurified test protein to form a first test mixture;
- (d) contacting the first test mixture with an exchange buffer comprising a denaturant and deuterium to form a second test mixture, the exchange buffer having a denaturant concentration;
- (e) contacting the second test mixture with a mass spectrometry matrix medium;
- (f) determining a change in mass of the test protein of the second test mixture resulting from hydrogen-deuterium exchange by mass spectrometry;
- (g) varying the denaturant concentration of the exchange buffer;
- (h) repeating steps (a)-(g) a number of times to generate a denaturation curve of the test protein; and

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- (i) analyzing the change in mass of the test protein resulting from hydrogen-deuterium exchange as a function of denaturant concentration in the presence of the test ligand as compared to a change in mass of the test protein resulting from hydrogen-deuterium exchange as a function of denaturant concentration in the absence of the test ligand, wherein a difference in the changes in mass of the test protein as a function of denaturant concentration is indicative of a binding event involving the test protein and the test ligand.

Please replace claim 125 with the following amended claim -

125. A method of detecting a binding event involving a test protein with a test ligand, the method comprising:
- (a) providing a test protein;
 - (b) providing a test ligand;
 - (c) contacting the test ligand with the test protein to form a first test mixture;
 - (d) contacting the first test mixture with an exchange buffer comprising a denaturant and deuterium to form a second test mixture for a specified time of exchange (t), the exchange buffer having a denaturant concentration;
 - (e) contacting the second test mixture with a mass spectrometry matrix medium;
 - (f) determining a change in mass of the test protein of the second test mixture resulting from hydrogen-deuterium exchange by mass spectrometry;
 - (g) varying the denaturant concentration of the exchange buffer;
 - (h) repeating steps (a)-(g) a number of times to generate denaturation curves of the test protein; and
 - (i) analyzing the change in mass of the test protein resulting from hydrogen-deuterium exchange as a function of denaturant concentration and the specified time of exchange (t) in the presence of the test ligand as compared to a change in mass of the test protein resulting from hydrogen-deuterium exchange as a function of denaturant

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concentration in the absence of the test ligand, wherein a difference in the changes in mass of the test protein as a function of denaturant concentration is indicative of a binding event involving the test protein and the test ligand.

2. The following is an examiner's statement of reasons for allowance: no prior art teaches or fairly suggests detecting a binding event between a test protein and a test ligand using a change in mass of test protein resulting from hydrogen-deuterium exchange as a function of denaturant concentration in the presence of the ligand compared to the mass change of test protein resulting from hydrogen-deuterium exchange as a function of denaturant concentration in the absence of the test ligand. The closest prior art is the reference of Ragonal et al. (J. Mol. Biol. (1999) Vol. 293, page 953) where Ragonal et al. teach using NMR to study a purified protein stability by exchange of hydrogen-deuterium of the purified protein. Ragonal et al. do not teach or suggest using mass spectrometry to detect a binding event between a test protein and a test ligand using mass change of test protein resulting from exchange of hydrogen-deuterium as a concentration of a denaturant.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu
Examiner
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July 21, 2006


LONG V. LE 07/24/06
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